MINUTES OF THE PUBLIC HEALTH COUNCIL

MEETING OF MAY 12, 2010

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

THE PUBLIC HEALTH COUNCIL OF
MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
Henry I. Bowditch Public Health Council Room, 2nd Floor
250 Washington Street, Boston, MA

Docket: Wednesday, May 12, 2010, 9:00 AM

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1. ROUTINE ITEMS: No Floor Discussion

a. Compliance with Massachusetts General Laws, Chapter 30A, §11A ½ **(No Vote)**

b. Record of the Public Health Council Meeting of April 14, 2010 **(Vote)**

2. PROPOSED REGULATIONS: No Floor Discussion/Information Only (No Votes)

a. Informational Briefing on Proposed Amendments to 105 CMR 650.000: Hazardous Substances (Implementation of a Limited Ban on Bisphenol -A in Children's Food and Beverage Containers)

b. Informational Briefing on Proposed Amendments to 105 CMR 590.000: Minimum Sanitation Standards for Food Establishments, Requiring Signs with Graphic Tobacco Health Care Warnings and Cessation Information

3. REGULATION: No Floor Discussion

Request for Final Promulgation of Emergency Amendments to 105 CMR 100.000: Determination of Need (Regarding Nursing Home Filing Dates) **(Vote)**

4. COMPLIANCE MEMORANDUM:

Previously Approved Project Application No. 2-3B53 of Heywood Hospital – Request for a significant change to increase the project's maximum capital expenditure **(Vote)**

5. PRESENTATION: No Vote/Information Only

The Commissioner and the Public Health Council are defined by law as constituting the Department of Public Health. The Council has one regular meeting per month. These meetings are open to public attendance except when the Council meets in Executive Session. The Council's meetings are not hearings, nor do members of the public have a right to speak or address the Council. The docket will indicate whether or not floor discussions are anticipated. For purposes of fairness since the regular meeting is not a hearing and is not advertised as such, presentations from the floor may require delaying a decision until a subsequent meeting.

PUBLIC HEALTH COUNCIL

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on May 12, 2010, 9:10 a.m., at the Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts in the Henry I. Bowditch Public Health Council Room. Members present were: Mr. John Auerbach, Commissioner, Department of Public Health, Ms. Helen Caulton-Harris, Dr. John Cunningham, Dr. Michéle David, Dr. Muriel R. Gillick, Mr. Paul J. Lanzikos, Mr. Denis Leary, Ms. Lucilia Prates Ramos, Mr. Josè Rafael Rivera, Dr. Meredith Rosenthal, Mr. Albert Sherman, Dr. Michael Wong, Dr. Alan C. Woodward, and Dr. Barry S. Zuckerman was absent. There is one vacancy. Also in attendance was Attorney Donna Levin, General Counsel.

Chair Auerbach announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance. He summarized the agenda items that would be heard.

RECORD OF THE PUBLIC HEALTH COUNCIL MEETING OF APRIL 14, 2010:

Mr. Albert Sherman moved approval of the minutes of April 14, 2010. Dr. Alan Woodward noted that there were some typos to be fixed and that he would give the information to the Secretary of the Public Health Council for correction. After consideration, upon motion made and duly seconded, it was voted unanimously (except Ms. Lucilia Prates Ramos not present to vote) to approve the Record of the Meeting of April 14, 2010 with typos corrected.

PROPOSED REGULATIONS:

INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO 105 CMR 650.000: HAZARDOUS SUBSTANCES

(IMPLEMENTATION OF A LIMITED BAN ON BISPHENOL -A IN CHILDREN'S FOOD AND BEVERAGE CONTAINERS):

For the record, Council Member Lucilia Prates Ramos arrived here just in time to hear Mr. Wilkinson's presentation below.

Mr. Geoff Wilkinson, Senior Policy Advisor, Commissioner's Office, accompanied by Attorney Jim Ballin, Deputy General Counsel, Office of the General Counsel, DPH, presented the proposal on BPA to the Council. Mr. Wilkinson noted verbally and in his memorandum to the Council dated May 4, 2010: "…This is to inform the Public Health Council members about BPA and to introduce the Department's draft regulation banning BPA pursuant to the Governor's directive. Bisphenol A is a chemical in polycarbonate plastic and epoxy resins widely used for producing food containers, including baby bottles, spill-proof cups, and infant formula packaging. A large number of studies in laboratory animals have raised concerns about potential health effects of BPA, particularly for the developing fetus and in nursing or formula-fed children who may be exposed to BPA. In August of 2009, DPH issued a consumer advisory that warned pregnant women and mothers of young children to avoid the use of products containing BPA for making or storing infant formula and breast milk. Consumer advocates are urging the administration to ban a wider array of products containing BPA, including baby food and infant formula containers and reusable bottles, such as sports bottles and thermoses. Representatives of the plastics, toy, infant food, chemical, and medical device industries are opposing regulation of BPA, citing concerns about economic impacts and maintaining that BPA is safe."

Mr. Wilkinson noted, "The proposed Massachusetts ban is modeled after a legislative ban on BPA in reusable baby bottles and non-spill cups intended for use by children under age three that was signed into law in Minnesota in 2009. The Massachusetts ban will apply only to reusable bottles or cups that contain BPA and that are designed and intended to be filled with food or liquid and used by children ages three years and under. Implementation of the ban will be phased in over the next year – apply only to children's reusable food

and beverage containers sold or distributed wholesale in Massachusetts by manufactures after January 1, 2011, or sold at retail after July 1, 2011. This will allow manufacturers to remove BPA-containing reusable children's food and beverage containers in Massachusetts with an additional six months for retailers to take appropriate steps to eliminate such containers from store shelves."

Mr. Wilkinson informed the Council that "Massachusetts was the first state to issue a formal consumer advisory about BPA in August of 2009 that is still in effect. The advisory warns against using products such as baby bottles that contain BPA for making or storing infant formula and breast milk. The advisory provides specific information about how to recognize products that contain BPA, describes alternative products available, recommends safe practices for the preparation of infant formula, provides information about the increased risk of exposure to BPA in canned liquid infant formula, and states that glass and stainless steel bottles and containers are BPA free. The advisory also recommends that pregnant and nursing mothers consider reducing their own exposures to BPA."

"Five other states have passed laws banning BPA, including Minnesota, Connecticut, Wisconsin, Washington, and Maryland. Eighteen other states, including California, New York, Illinois, and Michigan, currently have BPA legislation pending…" stated Mr. Wilkinson.

Staff's memorandum to the Council indicates that the proposed amendments include two technical changes to remove outdated language and correct an omission in the regulations. The two technical changes are: (1) To delete the provisions regarding the repurchase of urea formaldehyde foam installation (UFFI) 105 CMR 650.222 because the deadline to submit UFFI repurchase requests ended in 2000; and (2) to correct a previous drafting error in which part of the definition of 'toxic' was left out. Specifically, the definition of 'toxic' in the current regulations is based on the definition in the federal Hazardous Substances regulations, but includes only the 'acute toxicity' part of the definition while omitting the 'chronic toxicity' part of the definition. The proposed amendments would

include the full definition of 'toxic' to be consistent with the federal definition."

In closing, staff noted that the ban follows similar action in five other states and two nations that have already taken precautionary action to limit exposure of fetuses, infants, and young children to potentially harmful health effects of low-dose exposure to BPA. It is consistent with current FDA guidance and represents a limited, incremental regulatory approach that is science-based, poses no identifiable threat to employment or economic activity in the state, and is unlikely to be subject to federal preemption, should Congress act on one of the BPA bills presently under consideration."

No Vote/Information Only

INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO 105 CMR 590.000: MINIMUM SANITATION STANDARDS FOR FOOD ESTABLISHMENTS, REQUIRING SIGNS WITH GRAPHIC TOBACCO HEALTH CARE WARNINGS AND CESSATION INFORMATION:

Dr. Lois Keithly, Director, Massachusetts Tobacco Cessation and Prevention Program, made introductory remarks. She noted that the Tobacco industry spend over 242 million dollars in 2006 on point of purchase advertising (using area around the cash register for advertising) and further that the smokeless tobacco companies spend almost 21 million on point of purchase advertising in the retail store. In closing, she noted, "The Institute of Medicine Report in 2007 argued that the retail environment must be transformed from a site that promotes tobacco use to a site that promotes public health, and the report identified the area around the cash register as being the prime marketing space."

Ms. Eileen Sullivan, Director of Policy and Planning, Massachusetts Tobacco Cessation and Prevention Program, described the proposed regulation to the Council. She said in part, "We propose amending 105 CMR 590.000 to integrate public health messages at the point of purchase in the retail environment. First, we propose a new code

section, which will require a graphic warning sign on the health impact of tobacco and require a cessation education sign, designed to link tobacco users to available resources, such as our Quit Line. Second, we propose loosening design restrictions for the currently required youth access sign. This would allow DPH to create a more effective low literacy message to prevent illegal sales of tobacco to minors. Tobacco packs have long been used to convey health and cessation messages. Over thirty countries, including the European Union and Australia, require graphic warnings on cigarette packs. Under the authority to regulate tobacco products, the FDA will soon require larger graphic warnings on cigarette packs and smokeless tobacco, replacing the current warnings. The warnings will also apply to tobacco advertisements. States are preempted from further controlling pack design. However, including information in the retail environment is permissible and complements federal actions…Graphic warnings combined with cessation information, such as the Quit Line number, have been shown to make smokers more likely to think about quitting. Requiring graphic warnings in the retail environment is a population-based strategy that is broader than requiring on-pack warnings. On-pack warnings are usually only seen by the smokers, where the general population will be exposed to a health message in the retail environment. We believe that graphic warnings can impact the purchasing choices of potential tobacco users, including youth, and the signs support programmatic efforts to denormalize tobacco use."

Ms. Sullivan noted further, "The Institute of Medicine suggests including health and cessation messages at the point of purpose to offset tobacco advertising during the decision making process. The signs provide support to tobacco users seeking to quit in response to seeing the graphic warning and the increased promotion of the State's cessation resources through the signs should lead to increased utilization of those resources."

Ms. Sullivan explained, "…Both the graphic warning and the cessation education sign will be eight and a half by eleven and posted near the display of tobacco products. In the rare cases where tobacco is not displayed, a six by eight sign will be provided to place on the cash

registers. In an establishment with three or more cash registers, the six by eight versions of the graphic warning sign must be posted on all cash registers where the tobacco can be purchased. We want to ensure that everyone sees the warnings prior to purchasing tobacco and all cash registers will be required to have a three by three cessation education sign with the Quit Line number..."

Ms. Sullivan continued, "The second proposal involves our current youth access sign. The purpose of the current youth access sign is to inform retailers and the public that the sale or gift of tobacco to minors is prohibited and subject to fines under state law. The current wording tightly controls the design which limits DPH's ability to develop an effective low literacy message. The proposed change allows DPH broad discretion in developing a low literacy format to convey the message. The text required by Mass. general law is still included, but can be sized differently to allow more flexibility in sign design. The sizes of the signs will remain the same. Our experience with retailers has shown that they work in the retail environment…"

Discussion followed by the Council. Please see the verbatim transcript for full discussion. Mr. Josè Rafael Rivera suggested that the campaign include information on smokeless tobacco products. Dr. Muriel Gillick suggested that the signs be changed periodically so that the effectiveness of the warning signs do not wear off since people notice things the first few times and then it doesn't phase them anymore. Ms. Sullivan stated that the proposed regulations are written very broadly so that these two suggestions could be accommodated. Dr. John Cunningham suggested that staff be more specific about the language requiring the placement of the signs, specifically the regulations should say 'within the site line of the transaction' not just indicate within two feet.

Chair Auerbach noted that staff should discuss this suggestion during the comment period. Dr. Alan Woodward concurred with Dr. Gillick's suggestion of rotating the signs. It was noted that there are over 9,000 tobacco retailers in Massachusetts at this time. In response to Ms. Helen Caulton-Harris' question about who will enforce the regulation, Ms. Sullivan noted that they are having conversations with

the Massachusetts Health Officers Association about enforcement of the regulations by the local boards of health, of which 130 are funded by the MTCP, who will now focus on enforcement of this regulation for the next year or so. MTCP will give money to the Mass. Health Offices Association to help with enforcement. MTCP will be receiving the money from the CDC. Ms. Caulton-Harris further suggested that the signs be in appropriate languages for the neighborhood populations. Dr. Michele David said she concurred with Ms. Caulton-Harris regarding the language issue for the immigrant populations that do not speak English. Ms. Prates Ramos suggested that staff have focus groups with community providers so that the message on the signs is culturally appropriate and sensitive to the various communities. Mr. Denis Leary asked if the small business owner is part of the planning process for input on the sign development. Ms. Sullivan noted that in the past they have held focus groups with retailers. In addition, the local boards of health inspectors receive feedback from retailers. Ms. Sullivan emphasized, "We provide funding to 130 boards of health, covering about 60% of the retailers, the boards of health conduct two inspections a year and we will ask them to do three over the next year, so they will be in the stores more frequently and be able to implement this regulation." During discussion Mr. Paul Lanzikos noted that he hopes staff will come-back to the Council with an overall strategy for sustainability of enforcement of the regulations.

Mr. Rivera said he would like to hear a presentation from the HOPE Coalition, a youth group from central Worcester that has effectively spoken to the City Council there about capping the number of tobacco licenses awarded in the city. Chair Auerbach said in closing the discussion, "I would just summarize this by suggesting that, at the end of the public comment period, when we come back for a vote by the Council, if time allows and resources allow, it sounds like it would be great to have a little bit more detail on the specifics of the implementation. Maybe again, if time and resources allow, I heard suggestions that we might see some examples of what the signs would look like, with perhaps some of them speaking to the non-smoking related tobacco products, perhaps some speaking to different languages and different cultural approaches to the graphics,

and perhaps some altering the graphic with the not-so graphic. Again, I know it is resources and time, but I think, my hunch is that people will enjoy seeing whether some of their suggestions could be incorporated into some of the draft models."

It was noted that the hearings will probably be held in late June with the final regulations coming back to the Council in August.

REGULATION: REQUEST FOR FINAL PROMULGATION OF EMERGENCY AMENDMENTS TO 105 CMR 100.000: DETERMINATION OF NEED (REGARDING NURSING HOME FILING DATES):

Ms. Joan Gorga, Director, Determination of Need Program, accompanied by Dr. Alice Bonner, Director, Bureau of Health Care Safety and Quality and Attorney Carol Balulescu, Deputy General Counsel, Office of the General Counsel, addressed the Council. Ms. Gorga stated in part, "…I am here to request Council's action on the final promulgation of the amendments to 105 CMR 100.000 that were approved for emergency promulgation by the Council at the March meeting. As the surplus of nursing home beds has continued to increase, the Department has extended the filing date for new nursing home beds six times since the last filing date in 1990. The current projections presented to Council in March continue to show a surplus of beds through 2015. In fact, the projections show a surplus of over 10,000 long term care beds. The extension of the filing date means that the Department will not accept any applications for new nursing home beds until 2015." Staff noted that the regulations also contain a technical correction to the definition of expenditure minimum, which clarifies that the 25 million dollars for outpatient projects was added by Chapter 305 of the Acts of 2008 is adjusted annually as the other expenditure minimums…This was omitted from the original amendments last year and we are making that technical correction."

Ms. Gorga further noted that they held a public hearing on April 12, 2010 and no one attended the hearing, but staff did receive two written comments on the nursing home bed amendments. One came

from Mass. Home Care, which was supportive of the continued moratorium; the second comment was from the Massachusetts Senior Care Association, who, asked the Department to consider limiting the DoN filing date moratorium to two years rather than five years, and to add a regulatory provision that would allow DoN filing for new beds, if warranted, by excessive nursing home closures in one geographic area. Staff's response to the comments: "The current bed need projections show a surplus of over ten thousand beds. The actual surplus of beds is over five thousand beds. In other words, there are five thousand empty beds at the present time, thus a significant number of existing facilities would need to close to change the surplus. Most of the closures that we see are in very small facilities. They are not the 120 or the 240 bed nursing homes. Staff will continue to monitor bed need and can choose to act if the bed need projections are not accurate by amending the regulation on an emergency basis if necessary; we amended them on an emergency basis two months ago. Staff is therefore recommending that the amendments to be promulgated in final form with no changes."

Dr. Bonner responded to Dr. Alan Woodward about the Mass Senior Care Association's response to these regulations. Ms. Bonner said the Association is fine with this current version.

Mr. Albert Sherman moved approval of the regulations. After consideration, upon motion made and duly seconded, it was voted unanimously (Mr. Paul Lanzikos recused) to approve **the Final Promulgation of Emergency Amendments to 105 CMR 100.000: Determination of Need (Regarding Nursing Home Filing Dates).** A copy of the approved regulations is attached and made a part of this record as **Exhibit No. 14, 947.** As approved, these amendments move the filing date for applications for construction of new nursing home capacity to May 1, 2015 and make a technical correction to the definition of "expenditure minimum".

COMPLIANCE MEMORANDUM: PREVIOUSLY APPROVED PROJECT APPLICATION NO. 2-3B53 OF HEYWOOD HOSPITAL

– REQUEST FOR A SIGNIFICANT CHANGE TO INCREASE THE PROJECT'S MAXIMUM CAPITAL EXPENDITURE:

Ms. Joan Gorga, Director, Determination of Need Program, presented the Heywood Hospital request to the Council. "Heywood Hospital is before you this morning for a significant change to its capital construction project approved in August 2008. The hospital is requesting an increase in the maximum capital expenditure for the build-out of shell space to accommodate the relocation of 25 existing acute care beds. The 16,000 gross square feet of shell space is part of the three level 72,000 gross square foot addition approved in 2008. The requested maximum capital expenditure of $37,600,000 (March 2010 dollars) is an increase of $989,335 (March 2010 dollars) or 2.7% more than the inflation adjusted maximum capital expenditure of $36,610,665 (March 2010 dollars). The increase is related entirely to the build-out. The applicant has realized construction savings on the other parts of the project and without these savings, the request for the build-out would be 9% above inflation rather than only 2.7%."

Ms. Gorga continued, "By constructing now, the applicant will utilize construction personnel already on site for the original project, and the original project and the build-out will be completed at the same time, before the expected completion date of the original project. Staff has recommended community health initiatives for the increased MCE, and those initiatives are approximately an increment of $44,917, which will be developed collaboratively with the Office of Healthy Communities. Staff is recommending approval of the significant change." Daniel Moen, the President/CEO of Heywood Hospital and James Mullen, Chief of Clinical Nursing and Chief Operating Officer of Heywood Hospital along with their Attorney Alan Einhorn were present for questions. The Council had no questions.

Mr. Albert Sherman moved approval of the significant change. After consideration, upon motion made and duly seconded, it was voted unanimously (except Mr. Rivera who recused himself) to approve the **Request for Significant Change by Previously Approved Project Application No. 2-3B53 of Heywood Hospital to**

increase the project's maximum capital expenditure to $37,600,000 (March 2010 dollars). This amendment is subject to the following conditions:

1. Heywood Hospital shall provide $44,917 in community initiatives based on an increase of $989,335 (March 2010 dollars) in the maximum capital expenditure as described in the request for significant change. The community initiatives will fund programs that address local and regional health priorities in areas of need as assessed by the Office of Healthy Communities. Specific initiatives will be developed collaboratively by the Office of Healthy Communities and Heywood Hospital (within a reasonable time frame not to exceed three months) and may include mini grants, community capacity building, training and evaluation.

2. All other conditions attached to the original approval of this project shall remain in effect.

PRESENTATION: "BIRTH OUTCOMES IN MASSACHUSETTS: TRENDS AND DPH RESPONSES":

For the record, Council Member Dr. John Cunningham left the meeting at the start of this presentation at approximately 10:45 a.m. and Council Member Dr. Meredith Rosenthal left during the presentation at about 11:15 a.m.

Lauren A. Smith, M.D. Medical Director, Mass. Department of Public Health and Vanitha Janakiraman, M.D., Fellow in Maternal Fetal Medicine, Department of Obstetrics and Gynecology, Massachusetts General Hospital, presented birth outcomes data to the Council.

Some statistics from Dr. Smith's Powerpoint presentation follow: a comparison of a set of birth indicators for 2000 and 2008:

- The overall number of births has gone down and continues to go down: From 81,582 in 2000 to 76,969 in 2008 (-5.7%)

- The proportion of foreign-born mothers has gone-up and continues to go up; It was 15% in 1990, 20.8% in 2000 and was at 28% in 2008
- 34% of births were to non-white women, an increase of 26% from several years ago
- The teen birth rate has gone down and continues to go down (from 25.9% in 2000 to 20.1% in 2008)
- Preterm birth rates (<37 weeks) are stable with some fluctuations year to year
- Smoking during pregnancy is going down from 9.7% in 2000 to 6.9% in 2008
- Almost a 43% increase in gestational diabetes (2.8% in 2000 to 4.0% in 2008)
- Increase in cesarean deliveries (from 23.4% in 2000 to 34.3% in 2008) an increase of 46.6%
- Massachusetts has a low infant mortality rate compared to other states but there are significant disparities with the white rate being stable, the Black and Latino rates have been and remain higher and the Latino and Black rates may be going up again
- The highest infant mortality rates are in the 30 largest communities in Massachusetts

Dr. Smith noted further that the Department of Public Health will undertake an effort to review infant mortality on a statewide basis which has not been done before by the Department and said in part, "We thought if we are going to be serious about our work at looking at the reduction of infant mortality and specifically the reduction of disparities in infant mortality, we needed to have an explicit conscious and thoughtful statewide approach to doing that…The purpose is to decrease the incidence of preventable infant deaths in Massachusetts…We want to try to understand specifically in regions, in cities across the state, what are the contributions to infant mortality so that we can better design and implement the programs that we have in place. We want to be sure to complement and not duplicate the work of the birth defects program, which already is looking at reviews of these kinds of issues, as well as the state and local child fatality review teams which already look at some infant deaths…Clearly, a key part of this, to be effective, has to do with the

partnership and collaboration with the communities, where interventions and programs are going to have to be implemented."

Dr. Smith said further, "Our process initially and we are still in process is looking at surveillance review of all infant deaths that meet our case definition. We are going to use birth certificates and death certificate data. We will then do an in-depth review of a sub-sample of infant deaths, selected using the perinatal periods of risk approach…We will then be able to target maternal interviews and do medical record abstraction…and then, ideally, we will be developing recommendations, and then strategies to work with local communities…We will map the deaths according to these criteria. We will stratify them…This will allow us to look at the trends across the State and also by region. We could look at Boston, Springfield or Worcester because there may be different patterns in different regions that would lead to different understanding of where the implementation of policies and programs need to go."

In closing, Dr. Smith stated, "We understand that there are these persistent disparities. We are trying very hard to be able to do something about it so that we can come back to you at some point in the next year or two and be able to say we have done this. We have done the analysis and this is how we have realigned and restructured our program to attack different kinds of causations in different communities, and we really think that this is going to be complementary to build upon the work that is already being done in some of these communities, but enable us to broaden it to the whole state and not just some communities."

Dr. Vanitha Janakiraman of Massachusetts General Hospital made a Powerpoint presentation before the Council on variation in the rate of cesarean deliveries in Massachusetts hospitals. Some excerpts from her presentation follow:

"…The rate of cesarean delivery is rising and more and more women are having a baby by cesarean delivery…The rate declined in the 1990s reaching a low point of 19% and then, has been steadily increasing since then and our current rate is 34%, having stabilized a

little bit compared to what it was in early 2000 but it still seems to be on the rise. There are multiple contributing factors for this, and this is part of why it is hard to get a handle around this problem, and all of the contributing factors also affect each other. Hospital factors may play a part, some physician factors; individual physicians have very different rates of cesarean delivery. Patient preference, patient sociodemographics, medical conditions, labor complications and risk factors play a role as well."

Dr. Janakiraman continued, "We divide perinatal hospitals in Massachusetts into three levels. Level I hospitals generally take care of low risk women, who are likely to make it to 35 weeks of gestation or beyond. Level II hospitals take care of women who will deliver at least 34 weeks (IIA) or 32 weeks (IIB) and Level III hospitals are prepared to take care of any woman at any gestational age. Here in Massachusetts it is unique that our Level III hospitals deliver almost half of the babies in Massachusetts, and these are clustered into only nine hospitals…What is striking here is that Level I hospitals do take care of lower risk women and so we may expect that their rate of cesarean delivery would be lower than Level II and III; but, again, looking back in time, there really wasn't as much of a difference between the different level hospitals and today we do see much more of a difference. We want to dig underneath that a little bit more. We chose our study period of looking at cesarean deliveries as a time when this rate of difference has been increasing, 2004 to 2006…Our goal is to use DPH's available data to help understand this variation in the rates of cesarean delivery in Massachusetts. We specifically wanted to look at hospital factors, size, volume, staffing, and labor and delivery practices that might be affecting cesarean rates, and our ultimate goal is to provide analyses that can inform policies, that can help us take action on this problem."

Dr. Janakiraman said further, "We boiled this down to three study questions. First, if we take just low risk women, is there still variation among the rates of cesarean deliveries in these hospitals? Second, if we add in some women with preexisting conditions or labor and delivery complications, do we still see this variation? And finally, if we do see this variation, what hospital characteristics are

associated with those low and high rates of cesarean delivery? We use hospital discharge as well as birth certification information and we can use this to find out whether a woman has any preexisting health conditions that might predispose them to cesarean delivery, and we can also find out if they develop any labor and delivery complications that might predispose them to cesarean delivery."

She continued, "Using this data, we came-up with our study design. We wanted to define a study population that, overall, was pretty low risk for cesarean delivery. Anyone who had a clear indication for cesarean we tried to exclude. Our study populations consists of singletons, no multiples and only women who did not have a prior cesarean delivery in the past, vertex presentation so no breach babies, a greater than 37 week term, no birth defects and born in one of the 49 Massachusetts hospitals in our study period. We then further subdivided our study population into those with no documented risk. So, these are women who have none of the preexisting conditions, or labor and delivery complications that we consider to be risk factors for cesarean deliveries. These are an extremely low risk set of women, as far as our data is concerned. Another category is any women who had at least one risk factor for cesarean birth but we are dealing overall with a low risk population. And then, within that any risk population, we are looking at various subgroups of interest. This is our total study population.

Dr. Janakiraman reported, "These are the rates of cesarean delivery in all the 49 hospitals, lined-up in a row, from lowest to highest, and you can see that our overall rate in our study population is 16.5%. We have managed to pick out a pretty low risk population compared to the overall rate of 34%, but we still do see significant variation from a low of 8.6% up to 24%, and this number is the same, no deviation, which tells us that there is significant variability within this group…And for women in the lowest risk category, women we would not expect to be having a cesarean delivery, we see that the rates are quite different, 0.2% to 6.3% during our study period and there still is variability between the hospitals. This argued that the variability is not only about the patients because these patients are all clearly low risk, and there must be other factors that are

contributing and we need to nail those down a little bit. We did the same graph for our patients with any risk and this is the really impressive area for variability, from a low of 16.7% percent to a high of 68%, and with a very high standard deviation. Women who do not have some risk factor have an even more variable risk of having a c-section, depending on which hospital they go to."

Dr. Smith added, "The rate is 70% at one particular hospital but we are not going to say the name." Dr. Janakiraman continued, "Hospitals could still argue, we have very different kinds of patients from the hospitals over there. So, we looked at this by hospital level. For Level I hospitals in Any Risk category, we see very dramatic variability in the rate of cesarean delivery ranging from 16% up to 62.5%. In other words, we see that for the Level I hospitals fall all the way along this continuum of rates for cesarean delivery…At Level II hospitals the range is 26.3% all the way up to 68% and the standard deviation is very high; in Level III hospitals, we see less variation, there are less Level III hospitals to vary, but 20 to 47%, and the highest rates are not happening in the Level III hospitals"

Dr. Janakiraman summarized, "Our preliminary conclusions from looking at this data is that, for women in our study population, which is again a low risk population, there still is significant variation in rates of cesarean delivery among the 49 hospitals and this variation persists even among the women with no documented risk, that 3% category of women so it is unlikely to be entirely explained by differences in patient characteristics. There is a larger hospital variation in patients who have any risk compared to those with no documented risk; and in terms of looking at hospital level, we see that there is more variability in rates in Level I and II hospitals, compared to Level III hospitals."

Dr. Janakiraman noted that their next steps are to adjust for patient risk factors using multivariate regression; Identify hospital factors associated with high and low rates of cesarean using multilevel logistic regression. She said some of the differences may be due to other factors such as staffing arrangements or induced versus spontaneous delivery etc. She ended with their goal: "Provide data

that could inform policies to reduce variation in cesarean rates in Massachusetts."

A brief discussion followed by the Council. Please see the verbatim transcript for full discussion. The Council was astounded by the information presented. Dr. Michael Wong asked, "Is there a way to control reimbursement rates based on normal vaginal deliveries versus a c-section because I suspect that some of this is being driven by economics, reimbursement to the institution?" Dr. Smith noted that staff obtains the information from birth certificates and hospital discharge information so they know who the payor is for the delivery. It was noted that some billing information is available in the discharge data by facility not by payor. Dr. Janakiraman added, "Reimbursement rates for vaginal delivery and cesarean delivery are similar but what can be different is the way practices are structured in terms of how the individual physician receives reimbursement for a particular delivery. For example, a physician may be paid by how many deliveries he/she does per shift, that can change the motivations in terms of scheduling or not scheduling the delivery and in terms of when and how that delivery takes place and that wouldn't be captured if you look at charges but would be captured if you look at a micro-level of payment practices." Dr. Meredith Rosenthal noted in part, "….The first thing I thought about is the question what changed in payment over this period that seems to have driven this? Maybe that is not the answer…Taking a policy view of this data may not be the most productive use of this data. What if you brought this data to the hospital and said you are at 68% and with all the other Level II hospitals we see this curve…What's going on? That could be powerful if possible." Dr. Woodward suggested looking at the top five highest and the five lowest to get an in-depth analysis. Chair Auerbach noted for the record that cesarean rates per hospital is public data and is available on the DPH website. Dr. Smith said that the regular report on-line doesn't stratify the lowest risk women as in this analysis presented today, it is more overall totals for the state. Dr. Woodward added, "…Somehow we have to get this information and this breakdown out by institution."

During discussion Mr. Paul Lanzikos suggested that staff seek funding for further analysis on this subject from the insurers' foundations "…because there is a real public interest that would be served here." Dr. Alan Woodward stated in part that he assumes the studies will show that staffing has a lot to do with this, many hospitals employ hospitalist that perform all the deliveries in the hospitals now, the liability issue and the structure of the payment system, what are the contracts that exist between the hospital and the insurers and the reimbursement rates? Chair Auerbach said the next steps should be to figure out what the appropriate actions steps are to try to address the situations where cesareans are being performed where they are not necessary."

Gestational Diabetes Mellitus In Massachusetts Opportunities and Challenges:

Dr. Lauren Smith addressed another topic, the issue of Gestational Diabetes Mellitus in Massachusetts. "For this ten year period 1998-2007, the prevalence has increased to about 60%. We need to understand what that increase is due to and it may be related to changing maternal characteristics in terms of age, body mass index, race/ethnicity distribution. We need to think about how we do that and what mechanism do we use for data investigation. We know a couple of things. One is that the Massachusetts birth certificate has limited information on specific risk factors for gestational diabetes and does not have information on treatment and health consequences so we are going to need to go elsewhere for that. The Massachusetts Hospital Discharge Data provides additional information. Gestational Diabetes is underreported and we have no population based postpartum data around women who are diagnosed with gestational diabetes at all…"

Dr. Smith spoke about the Department's PELL system (Pregnancy and Early Life Longitudinal Data System) which links birth certificates, fetal death reports, and hospital discharge records. She said their study questions are (1) how can linked data enhance surveillance for diabetes during pregnancy and post-partum? And (2) what factors are associated with GDM or pre-existing/chronic diabetes mellitus

(DM) using the Birth certificate, fetal death reports and hospital discharge data? Dr. Smith noted: "For the years 1998-2007, there were 780,693 unique deliveries, 34,497 (4.4%) of women had GDM reported on their birth certificate, fetal death report or hospital discharge data. The overall prevalence of GDM increased from 3.4% to 5.4%. The population attributable fraction for this time period is Race at 12.4%, Age at 23.1% (what age is the woman is), Parity at 4.4% (how may births had) and Plurality at 1.1% (multiples or not). The biggest factor is age. If older women were to have had their babies during their twenties, you would have had 7621 fewer cases of gestational diabetes…Since the late 1990s, more women are having their babies over the age of 30 than under 30 years of age. Women's pre-pregnancy weight overall has been increasing and their weight gain during pregnancy has been increasing so body mass index is going to be very important and could change these results."

In closing Dr. Smith said, "We want to make sure that gestational diabetes remains a major data analysis focus in Massachusetts." She noted some future endeavors for the Department: (1) implementing a new national birth certificate, (2) enhance coding of medical conditions on the birth certificate and (3) make sure we are utilizing all mechanisms that we can to get information about diabetes and gestational diabetes (4) add a specific question about follow-up treatment for GDM/DM to MA PRAMS (5) encourage clinical sites to review GDM incidence and follow-up protocols and (6) and add GDM/DM monitoring to all MA surveys (e.g., BRFSS).

She said, "We are presenting the data that this is an issue and the data arm of the Department is diving into that analysis and the programmatic and policy arms of the Department are also doing things now on the ground to sort of address it as we are trying to understand this more deeply."

Discussion followed by the Council. Please see verbatim transcript for full discussion. It was noted that health concerns for a woman with gestational diabetes is a much higher risk of developing regular diabetes postpartum and later in her life. The idea is to follow-up with the mother and not lose track of her after her six week

postpartum check-up, one that requires a bridge between obstetrical prenatal/perinatal care and the patient's primary care provider and that is why clinical guidelines are being developed to understand what sort of follow-up women need. For the infant there can be complications during pregnancy, being large in size so a c-section is required and after birth complications such as glucose problems. Another suggestion discussed is that maybe there can be some incentives for the large Level III hospitals to partner with communities to provide prenatal care where it is needed.

NO VOTE/INFORMATION ONLY

In closing, Chair Auerbach invited everyone to the Hinton Lecture. "This is the lecture that is done every year that highlights the importance of working to end disparities, racial disparities and also highlights the achievements that have been made in the African American and Black communities in terms of public health and clinical advances. Council Member Dr. Michéle David is being honored with the highest award that is given, the Hinton Award for her ongoing work. Dr. David will present her work. The Hinton Lecture is at 3:00 p.m. tomorrow at the Hinton Laboratory, the State Laboratory in Jamaica Plain."

Follow-up Actions Steps:

- MTCP campaign include information on smokeless tobacco products (Rivera, Sullivan, Keithly)
- MTCP campaign signs be changed periodically (Gillick, Sullivan, Keithly)
- Staff be more specific about the language requiring placement of the tobacco warning signs. This suggestion to be visited at the public hearing. (Cunningham, Sullivan, Keithly, Auerbach)
- Tobacco warning signs be in appropriate languages for the neighborhood populations (Caulton-Harris, David, Sullivan, Keithly)
- MTCP staff conduct focus groups with community providers for feedback on how the tobacco warning signs can be culturally appropriate and sensitive to the various communities (Prates-Ramos, Sullivan, Keithly)

- MTCP staff return to the Council with an overall strategy for sustainability of enforcement of the regulations (Lanzikos, Sullivan, Keithly)
- Have the HOPE Coalition of Worcester visit the PHC on Tobacco (Rivera, Auerbach)
- MTCP staff return to the Council with more detail on the specifics of the implementation and bring examples of what the signs would look like incorporating the Council's suggestions above (Auerbach, Sullivan, Keithly)
- DPH seek funding from insurers' foundations to do further analysis on c-sections in Massachusetts (Lanzikos, Smith, Janakiraman)
- Determine what the appropriate actions steps are to try to address the situations where cesareans are being performed where they are not necessary (Auerbach, Smith, Janakiraman)

The meeting adjourned at approximately 11:35 a.m.

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John Auerbach, Chair

LMH
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